

REMARKS

The forgoing Amendment is submitted in direct response to the comments made by the Examiner in the Advisory Action of August 12, 2008. In particular, the Amendment provides claim language (consisting essentially of) to limit the agents that overcome the unpleasant mouthfeel of the botanical to those set forth, for example, in claim 1 paragraph (c). In particular, claim 1 now provides that the unpleasant mouthfeel suppressing agent consists essentially of one or more partially hydrogenated vegetable oils or saturated fats, wherein the amount of the unpleasant mouthfeel suppressing agent is effective to suppress the unpleasant mouthfeel of the botanical.

In a previous Amendment, Applicants indicated that the amount of the partially hydrogenated oils or saturated fats was effective alone to suppress the unpleasant mouthfeel of the botanical. The previous Amendment was rejected on the ground that it failed to comply with the written description requirement. Applicants withdrew this term from the claims only because the identical term was not set forth in the Specification (i.e. there was no literal written description of the term).

However, Applicants note that previously submitted claim 55 employs the language "consisting essentially of" in subparagraph (c). This Amendment was previously entered and therefore considered to meet all requirements of 35 USC §112. Accordingly, Applicants have used the same language in claim 1 to eliminate any

possible objection under the written description requirement. Entry of the amendment of claim 1 is therefore deemed proper and is respectfully requested.

In a telephone discussion with Patent Examiner Chawla on December 11, 2008 Applicants not only discussed the technical objections to the claims, but also the prior art rejections based on Katsuragi in view of Seang. During that discussion, the undersigned indicated that the hard boiled composition of the present invention employed partially hydrogenated vegetable oils or saturated fats as the only agent that suppressed the unpleasant mouthfeel of the botanical. Examiner Chawla expressed the view that the term "comprising" in the preamble of the claim was broad enough to include other unpleasant mouthfeel suppressing agents, including the specific agent taught by Katsuragi. In addressing this concern, it should be noted that the language "consisting essentially of" is described in the following terms "by using the term 'consisting essentially of' the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention". (PPG Industries v Guardian Industries Corp., 156 F.3d 1351, 48 USPQ 2d 1351 (Fed Cir 1998))

The basic and novel properties of the claimed invention is the use of one or more partially hydrogenated vegetable oils or saturated fats to suppress the unpleasant mouthfeel of the botanical, which is included in the hard boiled candy composition.

The claimed invention requires an amount of the unpleasant mouthfeel suppressing agent that is sufficient to suppress the unpleasant mouthfeel of the botanical. The words "consisting essentially of" mean that this is the only unpleasant mouthfeel agent needed to suppress the unpleasant mouthfeel. The Specification contains several statements and examples showing support that the unpleasant mouthfeel of the botanical is suppressed by the partially hydrogenated vegetable oils or saturated fats alone without the use of other such agents in combination. Support can be found at page 3, lines 7-8; on page 3, lines 11-12; page 3, lines 16-17; page 5, lines 8-16; page 6, lines 19-25; and in all of the Examples beginning on page 8.

Referring to the Examples, it is indicated on page 8, lines 22-23 that formulas A-J are in accordance with the present invention. Formulas A-F are all directed to hard boiled candies without gum, while Formulas G-J are directed to hard boiled candies with gum, the only difference being that the latter candy includes a "gum solution". Each of the Examples include sugar, corn syrup, a botanical (i.e. Echinacea) or mineral (i.e. Zinc) and one of the unpleasant mouthfeel suppressing agents specifically identified in the Application (i.e. palm kernel oil or partially hydrogenated cottonseed oil). The sugar and corn syrup (carbohydrate) components clearly fall under subparagraph (a) of claim 1, in that they are ingredients employed to make a confectionery base. Echinacea is, of course, the botanical under subparagraph (b). The only other ingredient in each of these formulas is either palm kernel oil or partially hydrogenated cottonseed oil. Thus, the formulas each show a hard boiled candy composition (with or without the gum solution) where the only unpleasant mouthfeel suppressing agent is the palm kernel oil

or the partially hydrogenated cottonseed oil falling under subparagraph (c) of claim 1. Thus, Examples A-J are fully consistent with the language employed in the present claims ("consisting essentially of ") where the sole agent that achieves suppression of the unpleasant mouthfeel of the botanical is the partially hydrogenated vegetable oil or the saturated fat.

Example 2, and particularly Formula K, shows another hard boiled candy formulation that contains candy base, two botanicals (Echinacea and Siberian ginseng), a single unpleasant mouthfeel suppressing agent (palm kernel oil) and mint flavor, which is included under the category of a confectionery base. It is well within the skill of the art to use flavoring agents as part of a confectionery base in the making of hard boiled confectionery candy formulations. Formula L is similar to Formula K, except that instead of a botanical a mineral salt is present.

Example 3 shows six formulations (1-6) where the unpleasant mouthfeel suppressing agent is partially hydrogenated cottonseed oil. It is therefore submitted that the Specification and the numerous Examples provided in the Specification support the invention as claimed in that the partially hydrogenated vegetable oils or the saturated fats in the amounts stated in the claims are sufficient to suppress the unpleasant mouthfeel associated with botanicals such as Echinacea and Ginseng.

It therefore follows that the present claims do not embrace the taste masking agents described in Katsuragi. It is only the partially hydrogenated vegetable oil or

saturated fat of the present invention that provides sufficient suppression so that the unpleasant mouthfeel of the botanical is not experienced by the average consumer. The present invention does not need and specifically excludes the Katsuragi-type taste masking agents from the present claims.

In this regard, the preamble of claim 1 refers to “a hard candy composition comprising”. The term *comprising* is an open-ended term that includes the addition of other ingredients. However, it does not embrace unpleasant mouthfeel suppressing agents that are specifically limited by the “consisting essentially of” language in subparagraph (c), as discussed above. The term “comprising” allows other common ingredients to be included within the claimed composition. For example, as described in the previous examples, the hard-boiled candy composition can contain a “gum solution” so that the hard candy can provide a chewing gum experience to the consumer. The term “comprising” in claim 1 is broad enough to include a gum solution. However, this term cannot be relied on to cancel out specific language in the claim (“consisting essentially of”) that limits the unpleasant mouthfeel suppressing agent to those specifically set forth in claim 1.

The Examiner will note that claim 55 (similar to claim 1) has been amended to employ the words “consisting essentially of” in the preamble of the claim. This claim is therefore narrower in scope than claim 1.

It is therefore submitted that a proper construction of claim 1 and all of the pending claims is that the unpleasant mouthfeel suppressing agent, limited by the words "consisting essentially of", identifies one or more partially hydrogenated vegetable oils and saturated fats in the amounts set forth in subparagraph (c) which are effective by themselves to suppress the unpleasant mouthfeel of the botanical. With this claim construction, it is clear that the claimed invention is not obvious from the cited prior art.

Before discussing the prior art, it is noted that the term "unpleasant mouthfeel" has again been rejected under 35 USC §112 (second paragraph). This term is alleged not to have been specifically defined in Applicants' disclosure in such a way as to overcome the rejection. The term is stated to render the claim indefinite, because it is a relative term that may vary from person to person. In particular, the Examiner states that the term "unpleasant mouthfeel" is a relative term "where a flavor such as capsaicin might provide unpleasant mouthfeel for one individual, it might be desirable and pleasant for another". The basis of rejection under §112 appears to be that the average purchaser of the hard candy composition may or may not experience unpleasant mouthfeel, and therefore the term is indefinite. However, this is not a proper basis for rejecting the term as indefinite.

It is well established that patents are written for those skilled in the art to practice the invention, not the public. In re Storris 245 F.2d 474, 478, 114 USPQ 293,296-97(CCPA 1957). A decision of whether a patent is invalid for using a particular term requires a determination whether those skilled in the art would understand what is

claimed. Amgen Inc. v Chugai Pharmaceutical Co. LLP, 927 F. 2d 1200, 18 USPQ 2d 1016 (Fed. Cir. 1991) cert. denied 52 U.S. 856 (1991).

The term "unpleasant mouthfeel", independent of what is described in the application, would be known to those of ordinary skill in the art. It is a common term that is used in this art, and in other art fields as well. The term is not indefinite simply because some people have more tolerance for a particular sensation (i.e astringency) than others. The assessment that a particular botanical has an unpleasant mouthfeel is based on scientific research, including the use of focus groups to ascertain the public's reaction to the ingestion of a particular botanical. If enough people are deterred from ingesting the botanical because of its unpleasant mouthfeel, the investment in research and development to counteract the unpleasant mouthfeel is certainly warranted. It is not relevant that a particular person experiences or does not experience an unpleasant mouthfeel when ingesting a botanical. What is relevant is whether a person of ordinary skill in the art would understand the term, such as in this case.

Botanicals are known as crude vegetable drugs consisting of herbs, roots, leaves, bark or other plant material as distinguished from a refined or prepared vegetable product. Thus, botanicals, by definition are not refined to remove unpleasant mouthfeel generating ingredients and would be expected to have unpleasant mouthfeel side effects for at least some consumers. The present application lists numerous examples of such botanicals that are recognized by those of ordinary skill in the art. It is therefore submitted that when the proper test is applied requiring the skilled artisan to

determine whether the term “unpleasant mouthfeel” is definite, it is clear that the term is definite, and the metes and bounds of the claims would be understood by those of ordinary skill in the art.

The last rejection is based on 35 USC § 103 in which Katsuragi, the primary reference, is combined with Seang. Katsuragi teaches a particular class of bitterness-relieving agents, which are not disclosed or claimed in the present Application. Applicants recognize that the reference also teaches some of the Applicants’ materials as a solvent for bitterness-relieving agents. Seang is stated to teach the masking of the flavor of drugs by mixing them with a lipid. The Examiner concludes that Katsuragi, to the extent that it is modified by Seang, renders the claimed invention obvious to one of ordinary skill in the art. The rejection is hereby traversed and reconsideration is respectfully requested.

Katsuragi teaches a class of bitterness-relieving agents that, as discussed above, are excluded from the present claims. There can be no question that Katsuragi requires in the reference formulation what Applicants exclude from their formulation. The citation of Seang does not cure the deficiencies of Katsuragi. Applicants agree that Seang talks about lipid materials. One of ordinary skill in the art, aware of Seang, might select one of the lipid materials of that reference to combine with the bitterness-relieving agent that Katsuragi requires. The resulting composition still requires the bitterness-relieving agent, which is excluded from the present claims. So long as the

rejection is based on Katsuragi in view of Seang, the claimed invention is neither taught nor suggested by the combination of these references.

In addition, it should be noted that Seang is directed to a method of producing an aqueous stable drug composition in which the final form of the drug is a viscous syrup (page 10, line 8, and page 12 line 11). Thus the product for ingestion by the consumer is a syrup (liquid). To the contrary, the present invention is directed to a hard boiled candy composition. It is not in the form of a viscous syrup or any other type of liquid vehicle. There is no indication that the steps necessary to produce the liquid composition of Seang can be used to produce a hard boiled candy composition, particularly since Seang is concerned about stability requiring that the drug and lipid mixture be combined with a emulsifier, a polymer solution and a dilution solution (page 2, line 34 to page 3, line 2). The need for stability is mentioned, for example, at page 1, lines 25-28 and page 2, line 25.

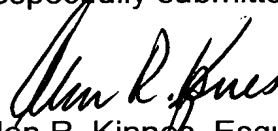
It is therefore apparent that Seang is directed to a different technology in which drugs are formulated in a stable liquid suspension for oral administration. Lipids are used to partially surround the granules of drug, but the composition must be in the form of a stable liquid. In the present invention, the composition is in the form a hard boiled candy composition (a solid), produced in an entirely different manner than the liquid composition required by Seang. One of ordinary skill in the art would not look to Seang for guidance for how to prepare a hard boiled candy composition, because the object of

the composition (i.e. a stable liquid drug composition) is far different than hard boiled candy compositions in which the botanical is not suspended in a liquid composition.

The present Amendment includes minor amendments to the claims. In particular, claims 2,4,5,29,31, and 32 have been amended to provide proper Markush language. Claim 8 has been amended to conform to original claim 35.

In view of the foregoing, Applicants submit that the present Application is in condition for allowance, and early passage to issue is therefore deemed proper and is respectfully requested.

Respectfully submitted,



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